IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: ETHICON WAVE 1 CASES LISTED IN EXHIBIT A	

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE THE PROPOSED TESTIMONY OF MICHAEL KARRAM, M.D. REGARDING THE SAFETY AND EFFICACY OF THE TVT-O PRODUCT

Plaintiffs in the above-captioned consolidated case respectfully move this Court to exclude the testimony of Defendant's expert witness, Michael Karram, M.D.,[1] related to Ethicon's TVT-Obturator product ("TVT-O"). Dr. Karram's opinions should be excluded because: (1) Dr. Karram has not used the TVT-O product for more than five years and did not even know the TVT-O product was still on the market; (2) Dr. Karram admitted during deposition he was not qualified as an expert in many areas where he purports to offer expert opinions; (3) Dr. Karram failed to review key internal documents regarding the history of the product's design, safety or efficacy; (4) Dr. Karram selectively reviewed literature and relied only on studies that were supportive of his opinion; (5) Dr. Karram makes improper assumptions about the intentions and knowledge of "all surgeons" and "all patients"; and (6) Dr. Karram has never subjected his opinions or methods to peer review. Finally, Dr. Karram's opinions do not fit the facts of this case because his report is focused almost entirely on TVT-Retropubic and not

[1] To avoid confusion, it should be noted that Dr. Michael Karram's brother, Dr. Mickey Karram, has also served as an expert witness in various mesh litigations. Despite the similarity in their names and the fact that they both practice in Ohio, these are different experts with different qualifications, opinions and publication histories.

TVT-O. For these reasons, Dr. Karram's opinions do not satisfy the requirements for expert witness testimony as set forth in Rule 702 and under the *Daubert* standard and he should not be allowed to testify as an expert witness.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions. The rule reads, in pertinent part, as follows:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied principles and methods, and (3) the witness has applied principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. On the issue of qualifications, "the district court must decide whether the expert has 'sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.'" *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012), *as amended* (May 9, 2012) (quoting *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999)).

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury—i.e., whether it is relevant. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). The relevance aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

To meet the standard of reliability, the testimony "must be supported by appropriate validation—i.e., 'good grounds,' based on what is known. In short, the requirement that an

expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability." *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1383 (4th Cir. 1995). The function of the Court is to act as a gatekeeper when it comes to expert testimony: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" and it is incumbent upon the Court to "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595).

There are five factors courts often consider, taken from the *Daubert* opinion, in assessing the reliability of expert testimony:

(1) whether the testimony has been tested,
(2) whether it has been published or exposed to peer review,
(3) its rate of error,
(4) whether there are standards and controls over its implementation, and
(5) whether it is generally accepted.

See Cavallo v. Star Enterprise, 100 F.3d 1150, 1158 (4th Cir. 1996). However, "the factors discussed in *Daubert* were neither definitive, nor exhaustive." *Cooper*, 259 F.3d at 199.

Courts should focus on expert witnesses' "principles and methodology, not on the conclusions that they generate." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). This is because "*Daubert* governs whether evidence is admitted, not how persuasive it must be to the factfinder." *Cavallo*, 100 F.3d at 1158. The court has considerable discretion in determining the admissibility of expert testimony and whether the expert should be admitted or excluded. "[T]he trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

ARGUMENT

I. DR. KARRAM IS NOT QUALIFIED TO PROVIDE EXPERT TESTIMONY.

Dr. Michael Karram is a practicing urogynecologist. Dr. Karram has never published an article in a peer-reviewed journal. In his deposition, he testified as follows:

> Q. So you've never published as an author in any peer-reviewed journal; is that correct?
> A. Correct.[2]

While in deposition, Dr. Karram testified that he is not an expert in most of the matters about which he has been designated to opine. He testified as follows:

> Q. You're not an expert in biomaterials; is that correct?
> A. No, that's correct.
> Q. You're not an expert in pathology?
> A. I would consider myself not an expert in pathology. ….
> Q. Have you ever designed a clinical study?
> A. No.
> Q. Would you consider yourself an expert in statistics?
> A. Far from it.
> Q. Would you consider yourself an expert in epidemiology?
> A. No.[3]
>
> ….
>
> Q. You don't hold yourself out as an expert witness in FDA regulations related to medical devices, do you?
> A. No.
> Q. You don't hold yourself out as an expert witness in marketing of medical devices, do you?
> A. No.[4]
>
> …
>
> Q. Would you consider yourself an expert in drafting instructions for use or IFUs?
> A. No. ….
> Q. Sure. Would you consider yourself or hold yourself out as an expert in the development of medical devices?

[2] Karram dep. 3/29/16 31:23-32:1 (Deposition of Dr. Michael Karram Attached as Exhibit B to Plaintiffs' Motion).
[3] Karram dep. 3/29/16 51:2-52:7.
[4] Karram dep. 3/29/16 50:19-51:4.

A. No.
Q. Would you consider yourself an expert in design of medical devices?
A. No.[5]

Further, in the CV Dr. Karram served with his Report, he represented that he was a "Primary Investigator – Clinical Evaluation of Gynecare Thermachoice III Uterine Balloon System." However, upon questioning, Dr. Karram admitted he was not a Primary Investigator and that Ethicon simply hired him to present the poster on the study.

A. I did not actually perform [that study]. I was a consultant on that, and I was listed as the investigator, and we presented that at one of the AAGL meetings in San Francisco, and so I was sked to discuss the study at the presentation it was a poster presentation.
Q. So when it says here in your resume "primary investigator," you were not actually a primary investigator?
A. I was not actually a primary investigator.
Q. You were a consultant on that?
A. Correct.[6]

With respect to the TVT-O device, Dr. Karram testified that he chose to stop using the TVT-O device more than five years ago. In fact, until just before his deposition, he believed that the TVT-O device was removed from the market five years ago. Dr. Karram testified as follows:

> When Abbrevo came out, I thought and I was under the impression that they weren't going to market the TVT-O anymore. And, in fact, I just found out last week from some doctors in Dayton that they still do. But at our hospital, we didn't stock it. Once Abbrevo came out, they stopped stocking TVT-O, and I just assumed that TVT-O was off the market, but apparently it isn't.[7]

The fact that Dr. Karram purports to be an expert on TVT-O yet didn't even know the product was still on the market and hadn't used it for over six years reflects that he did not approach this review with the rigor and comprehensive nature that the task requires.

Quite simply, Dr. Karram is not qualified to offer any expert opinions in this litigation. He has never published a scientific paper, let alone a paper regarding anything remotely related

[5] Karram dep. 3/29/16 51:8-23.
[6] Karram dep. 3/29/16 35:19-36-4.
[7] Karram dep. 3/29/16 89:12-19.

to this litigation. That is, he has never had any of his scientific opinions or methods subjected to peer review. Further, Dr. Karram misrepresented his experience in his CV that was served with his report, claiming he was a Principal Investigator for Ethicon when, in fact, he never participated in the study other than as a paid presenter of the study data. Moreover, Dr. Karram admits that he is not an expert in practically every field about which he proffers opinions. Finally, in the only area in which Dr. Karram might be qualified – a urogynecologist's use of the TVT-O device – Dr. Karram stopped using the TVT-O device more than five years ago and admitted that he thought the product had been removed from the market.

II. DR. KARRAM FAILS TO ADDRESS THE RELEVANT TVT-O SCIENCE, ONLY DISCUSSES SCIENCE THAT SUPPORTS HIS OPINIONS AND INCORRECTLY REPORTS THE RESULTS OF STUDIES HE DOES ADDRESS.

Rule 702 states that "A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if… the testimony is based on sufficient facts or data." Here, Dr. Karram was offered as an expert witness regarding the safety and efficacy of the TVT-O device. However, upon review of his Report, it is evident that his Report is focused on the TVT-Retropubic, not the TVT-Obturator device. Moreover, Dr. Karram admitted he only considered science that was supportive of his opinions. As Dr. Karram's opinions are not based on facts or data regarding the TVT-O, they should be excluded.

A. Dr. Karram Failed to Address the Science Regarding the TVT-O Device.

Dr. Karram was offered as an expert on the TVT-O device. However, Dr. Karram's Report discusses, almost exclusively, the TVT-Retropubic device. In fact, the word "obturator" appears a total of five times in his Report and only when he is generically discussing the trans-obturator approach as one of many alternatives for the treatment of stress urinary incontinence.

The name of the device in question, "TVT-O" or "TVT-Obturator," does not appear in his entire Report – not once.

Moreover, there are literally hundreds of scientific papers addressing the TVT-O device, including more than 21 randomized controlled clinical studies; yet, of the dozens of papers cited in his Report, only two papers even include the TVT-O as a device being studied. In fact, Dr. Karram does not even mention the pivotal TVT-O studies by the inventors of the device Drs. de Leval and Waltregny or discuss the unique feature of the TVT-O, the "inside-out" approach. The remaining literature throughout his Report concerns the TVT-R.

Similarly, Dr. Karram does not cite to, nor discuss, TVT-O specific complication rates, efficacy rates (aside from the two studies discussed above), nor the warnings specific to the TVT-O device. Instead, the data he does discuss is related to the TVT-R (and, as discussed below, the data and science he addresses on the TVT-R is largely wrong or cherry-picked to support his opinion).

While Dr. Karram's Report might contain sufficient facts and data regarding the TVT-R, clearly he fails to address sufficient facts and data related to the device for which he is being proffered as an expert, the TVT-O. Pursuant to Rule 702, Dr. Karram's opinions regarding the TVT-O should be excluded.

B. Dr. Karram Selectively Reviewed and Included Literature and Data.

As noted above, the majority of science and data Dr. Karram does address in his Report is related to the TVT-R device. However, even when addressing this data, Dr. Karram chose to address only science and data that supports his opinion. Such a methodology is unreliable and Dr. Karram's opinions should be excluded.

The Advisory Committee notes on Rule 702 state that one factor relevant in determining whether expert testimony is sufficiently reliable to be considered by the trier of fact is whether the expert has adequately accounted for obvious alternative explanations. *See Claar v. Burlington N.R.R.*, 29 F.3d 499 (9th Cir. 1994) (testimony excluded where the expert failed to consider other obvious causes for the plaintiff's condition). This Court has previously held that an "expert's opinion may be unreliable if he fails to account for contrary scientific literature and instead 'selectively [chooses] his support from the scientific landscape.'" *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *8 (S.D. W. Va. Sept. 29, 2014) (Goodwin, J.) (internal citation omitted).

During his deposition, Dr. Karram admitted that he used this unreliable methodology. Dr. Karram testified as follows:

> Q. Did you cite in your report any papers you felt didn't support your opinion but you analyzed why they wouldn't be applicable?
> A. No.
> Q. In your report, you only cite those papers that support your opinion, correct?
> A. Yes, for the most part, yes.[8]

When Dr. Karram was presented with data that was contrary or inconsistent with his opinion, he testified that he did not analyze or discuss in his Report why this contrary evidence did not undermine his opinions.

Dr. Karram's report is not a systematic review of the scientific literature, nor does it meet the standards of a systematic review. The method used by Dr. Karram in his report is scientifically unreliable cherry-picking. It stands in stark contrast to the methods used by most scientists in the field and in the reports of the experts this Court has previously permitted to testify.

[8] Karram dep. 3/29/16 77:9-16.

C. The Data Discussed in Dr. Karram's Report Is Almost Exclusively Related to the TVT-R and Much of It Is Incorrect.

Even the limited material Dr. Karram considered, reviewed and relied upon was presented incorrectly in his report. In numerous instances in his report, Dr. Karram presented and relied upon the wrong figures, data and results from various studies. For example, one of the slides Dr. Karram uses and relies upon in his report is from the Rezapour study published in 2009. This was a TVT-R study (not a TVT-O study), and the data Dr. Karram presented in his Report was incorrect – Dr. Karram's report listed the failure rate as 3 percent – not the correct failure rate of 9 percent.

> Q. If you look at the Rezapour study, Exhibit 9, Doctor, it says, "According to the protocol, 28 patients, 82 percent, were cured. 3 or 9 percent were significantly improved. And the operation failed in 3 cases or 9 percent." So your slide that you put in your expert report under values or understates the failure rate by -- it should be 9 percent, not 3 percent, correct?
> A. Correct.
> Q. So that slide has, it appears, two errors in it, correct?
> A. Yes, depending on the definition, and it should also be that this study was a study on TVT on women with recurrent stress incontinence, not the primary history; whereas, the others were primary procedures. They weren't done on recurrent, to my knowledge. They were follow-ups on all the primary procedures.
> Q. So that's another change you'd want to make on that slide is to make that notation?
> A. I would, yes.[9]

In another example, Dr. Karram lists in his Report data from five studies. Dr. Karram admitted that the studies all addressed the TVT-R, not the TVT-O, and that he incorrectly reported the results from the studies. He testified as follows:

> Q. And, again, this is citing five studies. Those are all only about the TVT Retropubic, not the TVT Obturator, correct?
> A. That's correct.
> Q. In the Olson study, the last Olson, with one S, do you see that?
> A. Yes.

[9] Karram dep. 3/29/16 109:5-24.

Q. The last one on the slide --
A. Yes.
Q. -- has various percentages; dry, 77 percent, improved, 18 percent; failed, 15 percent. That adds up to 110 percent. Do you have a sense of where the mistake is there?
A. No, I don't.[10]

In yet another mistake pointed out in his deposition, Dr. Karram testified it was incorrect and that he would like to fix his report. He testified as follows:

Q. And if that slide, indeed, reflects what it looks like it reflects, which is an increase in cure between months 12 and 24 to 36, it's incorrect?
A. If this slide was meant to be the slide in the original paper, yes.
Q. Yes, it's incorrect?
A. Yes, it's incorrect.
Q. And you would want to correct that in your report, correct?
A. Yes.[11]

In sum, Dr. Karram's Report fails to address any of the science and data related to the TVT-O device. As noted above, he does not even mention the TVT-O in his Report. Moreover, the data and science Dr. Karram does cite to is related to the TVT-R, selectively chosen to support his opinions and often reported incorrectly.

III. DR. KARRAM ADMITTED THAT HE FAILED TO REVIEW HUNDREDS OF RELEVANT STUDIES AND DOCUMENTS THAT WERE ERRONEOUSLY INCLUDED IN HIS LIST OF RELIANCE MATERIALS.

In addition to failing to review the relevant scientific literature, Dr. Karram also failed to review volumes of other relevant materials even though the materials were listed on his 18-page "Reliance List." This only became apparent when, during his deposition, Dr. Karram admitted he had not seen hundreds of documents that were on his Reliance List.

For example, Dr. Karram spends a significant portion of his Report discussing the adequacy and sufficiency of the TVT-O IFU and Ethicon's marketing brochures. When asked

[10] Karram dep. 3/29/16 106:3-16.
[11] Karram dep. 3/29/16 112:24-113:12.

about these documents during his deposition, Dr. Karram testified that he had not actually reviewed any of the more than 120 internal Ethicon documents on his Reliance List. In addition, he admitted that he had not actually reviewed the TVT-O IFUs that were listed on his Reliance List. He testified as follows:

Q. But even the prof ed ones that might be listed on here, you didn't specifically look at those in preparation of your report and rely upon those; is that fair?
A. No.
A. Correct.
Q. As a matter of fact, have you seen any documents where on the bottom right corner of the document it says ETH.MESH and there's a number?
A. No, not that I'm aware of.

…

Q. So December 15 into January 16, I'd like to focus on that time frame.
A. Okay.
Q. In that time frame and in preparing your report for this case, did you review any patient brochures?
A. No.
Q. In that time frame and in the preparation of your report for this case, did you review any IFUs for any of the TVT products?
A. No.[12]

This is not merely a theoretical concern. For example, in his Report, Dr. Karram opines that there is no difference between laser cut and mechanically cut mesh. He states "[t]here has been robust opportunity to assess for any difference in outcomes. None have been observed. Overall, this theoretical risk has led to no measurable clinical effect or risk."[13] Dr. Karram makes this statement without having reviewed a single page of the hundreds of pages of internal Ethicon documents discussing this very issue. He testified as follows:

Q. You've never seen any internal Ethicon documents discussing those differences between the laser-cut mesh and the mechanically-cut mesh, correct?
A. I have not.[14]

[12] Karram dep. 3/29/2016 80:14-81:18.
13 Report at 30-31 (Expert Report of Dr. Michael Karram Attached as Exhibit C to Plaintiffs' Motion).
[14] Karram, 3/29/2016, 91:14-18

Had Dr. Karram done a comprehensive review of the available documents and data, he would have seen data and internal Ethicon employee discussions about the many reports they received of particle loss, elongation and other differences between the two manufacturing techniques. As evidenced by numerous internal documents and presentations, Ethicon conducted testing on this very issue and presented data internally reflecting differences between the two techniques – data that Dr. Karram did not review. Reviewing the internal documents and data may not have altered his conclusions, but not reviewing the available data and materials reflects a flawed methodology.

Subsequent to his deposition, Plaintiffs' counsel requested a Reliance List reflecting what Dr. Karram actually reviewed and relied upon in issuing his opinions. In the "new" Reliance List provided by defense counsel, over half of the items were deleted, including 54 scientific papers, all of the TVT-O IFUs and all of the internal Ethicon documents.

Dr. Karram's failure to review the TVT-O IFUs, patient brochures and other relevant Ethicon internal documents is methodologically improper. Moreover, his belated deletion of hundreds of documents from his Reliance List violates this Court's Orders and the expert disclosure requirements under Rule 26. *See* Fed. R. Civ. Pro. 26.

IV. DR. KARRAM CANNOT TESTIFY AS AN EXPERT ABOUT HIS PERSONAL EXPERIENCES.

Throughout his Report Dr. Karram opines about very broad issues based on his limited personal experience. However, such personal experiences, when unsupported by a review of relevant documents and data, is not the proper subject of expert testimony.

In order to testify as an expert, Rule 702 states that the expert's scientific, technical, or other specialized knowledge must be used to help the trier of fact to understand the evidence or

to determine a fact in issue, and that this opinion must be based in fact. When evaluating relevancy, *Daubert* provides guidance on the admissibility standard:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted). Dr. Karram's *personal experience* with the training methods and materials used by Ethicon do not qualify as expert opinions.

For example, Dr. Karram states "Ethicon/Gynecare did an excellent job of educating surgeons on the use of their products. As mentioned above in this document, I served as lead faculty on many training sessions."[15] The only support Dr. Karram provides for this opinion is his own experience in a number of training sessions. As noted above, other than the materials he personally presented, Dr. Karram did not review any of Ethicon's training materials, internal training guidelines or standard operating procedures. In addition, he did not review any training by any other physicians or Ethicon employees. While Dr. Karram's personal experience may be interesting factual testimony, absent a more rigorous review of documents and data, it does not rise to the level of expert testimony.

In addition, in many instances in his report, Dr. Karram makes blanket and unsupported statements about what "all surgeons" and "all patients" knew or should have known. Aside from the impossibility of knowing what all surgeons and all patients know or are told, it is improper expert testimony and should be excluded. For example, Dr. Karram states "All patients are

[15] Report, at 25.

consented and understand the risks, benefits, options, complications, side effect, and results."[16] Similarly, Dr. Karram states in his report that "It is well known by all pelvic floor surgeons that any surgery for stress urinary incontinence or pelvic organ prolapse, with or without the use of mesh, can potentially cause complications that can be temporary or permanent, including but not limited to: pelvic pain, dyspareunia (pain with sexual intercourse), scarring, vaginal narrowing, leg/groin pain, urinary retention and other voiding problems."[17] When asked about these broad statements in his deposition, Dr. Karram admitted that he could not personally know what every single surgeon or patient knew or should know. He testified as follows:

> Q. In this section, you have a statement that starts -- the last phrase on this page saying, "It is well-known by all pelvic floor surgeons." Do you see that?
> A. Yes.
> Q. You don't actually know that, right, that it's well-known by all pelvic floor surgeons, correct?
> A. Well, I have never spoken personally with all pelvic surgeons, but I have worked with and trained a vast number of pelvic surgeons, and they are aware of certain things.
> ...
> Q. But you don't have any personal knowledge? You haven't spoken to all pelvic surgeons, correct?
> A. No, I have not.[18]

Had Dr. Karram reviewed any internal Ethicon documents or company witness depositions, he might have seen the numerous instances where Ethicon received notice from different patients that they were not properly consented and were not aware of the complications that could occur with these products. Dr. Karram should be excluded from discussing or testifying about what he believes all surgeons know or what conversations occur in all operating rooms between surgeons and patients. This is not proper expert testimony and is not supported

[16] Report at 27.
[17] Report at 6).
[18] Karram dep. 3/29/16, 113:19-114:17.

by any facts other than Dr. Karram's personal beliefs. Accordingly, Dr. Karram should not be permitted to testify as an expert about his personal experiences absent a more rigorous review of relevant documents and data. Moreover, his assumptions about the state of knowledge of physicians and patients around the world should be excluded.

V. CONCLUSION

Dr. Karram's opinions fail on all aspects of the *Daubert* inquiry. Dr. Karram did not employ a reliable methodology because (1) he did not review the majority of the literature regarding TVT-O; (2) he did not review any internal Ethicon documents related to safety, training or efficacy of TVT-O; (3) he only included and analyzed studies in his report that were supportive of his opinion and those studies he did include were frequently reported incorrectly in his report; (4) he has never subjected any of his methods or opinions to peer review; (5) he admits he is not qualified as an expert on several aspects of his report; and (6) he did not employ a reliable method as evidenced by the fact that he has not used the product for more than five years and did not even know the TVT-O product was still on the market until after he issued his expert report. Finally, Dr. Karram's opinions do not fit the facts of this case because his report is focused almost entirely on TVT-R, not TVT-O. Dr. Karram should not be allowed to testify in this matter, and Plaintiffs respectfully request the Court strike him as an expert entirely.

Respectfully submitted this 21st day of April, 2016.

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CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the list of participants registered to receive service in this MDL.

/s/ Sarah Peasley
Sarah Peasley